



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Bernd Riedl et al.

Serial No.: 10/042,226

Group Art Unit: 1614

Filed: January 11, 2002

Examiner: Dwayne C. Jones

For:  $\omega$ -CARBOXYARYL SUBSTITUTED DIPHENYL UREAS AS RAF KINASE INHIBITORS

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98**

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Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

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  - within three months of the filing date of a national application other than a CPA under § 1.53(d);
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  - before the mailing of a first substantive office action (including after filing of an RCE).
- Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
  - a final rejection under 37 C.F.R. 1.113;
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  - a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).
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#### Statements Under 37 C.F.R. 1.97(e)

- Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

#### Cited Materials

- Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. \_\_\_\_\_, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- Copies of materials listed but not attached were cited in an international search report dated \_\_\_\_\_.
- Not required by 37 CFR § 1.98.
- Copies of the materials listed are attached.

Non-English Language References

- An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
- A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

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Y = document of particular relevance when it is combined with another such document  
A = document defining the general state of the art  
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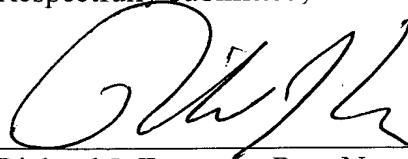
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The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



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Attorney Docket No.: BAYER-0024-A

Date: June 14, 2006

*RJT/jmj*

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 8

### Complete if Known

Application Number	10/042,226
Filing Date	January 11, 2002
First Named Inventor	Bernd RIEDL et al.
Group Art Unit	1614
Examiner Name	Dwayne C. Jones

Attorney Docket Number

BAYER-0024-A

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		4,546,191				
		5,559,137				
		6,380,218				
		3,284,433				
		5,510,094				
		6,310,068				
		6,525,046				
		6,500,863				

### FOREIGN PATENT DOCUMENTS

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		Office <sup>3</sup>	Numb er <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		EP	0690344					
		WO	02/092576					
		WO	02/062763	A2	Bayer Corp.	8-15-2002		
		WO	02/083628	A1	Boehringer Ingelheim Pharmaceuticals Inc.	10-24-2002		
		WO	02/085857	A2	Bayer Corp.	10-31-2002		
		WO	02/085859	A1	Bayer Corp.	10-31-2002		
		WO	97/09973		The Regents Of The University Of California	3-20-1997		
		WO	98/20868					
		WO	98/45268					
		WO	99/28305					
		WO	02/14311					
		WO	00/56331					
		WO	03/099771					
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Sheet	2	of	8	Attorney Docket Number	BAYER-0024-A

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
		Blanco, "p38 MAPK signaling cascades: ancient roles and new functions," Bioassays, 22:637-645, 2000		
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		Facts and Comparisons, 1994, 2703-2705		

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		Examiner Name	Dwayne C. Jones
		Attorney Docket Number	BAYER-0024-A

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		XP-002233466, MEDLINE/NLM, NLM8336809 - [Intra-arterial ACNU, CDDP chemotherapy for brain metastases from lung cancer: comparison of cases with and without intra-arterial mannitol infusion], Iwadate Y et al.	
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		Lowinger, T. B.; Riedl, B.; Dumas, J.; Smith, R. A. "Design and Discovery of Small Molecules Targeting Raf-1 Kinase" Curr. Pharm. Design 2002, 8 (25), 2269.	
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		Richly H, Kupsch P, Passage K, Grugert M, Hilger RA, Kredke S, Voliotis D, Scheulen ME, Seeber S, Strumberg D: "A Phase I clinical and pharmacokinetic study of the Raf kinase inhibitor (RKI) BAY 43-9006 administered in combination with doxorubicin in patients with solid tumors" Int. J. Clin. Pharm. Ther. 2003, 41(12), 620-621.	
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		Dumas, J.; Sibley, R.; Riedl, B.; Monahan, M.-K.; Lee, W.; Lowinger, T. B.; Redman, A. M.; Johnson, J. S.; Kingery-Wood, J.; Scott, W. J.; Smith, R. A.; Bobko, M.; Schoenleber, R.; Ranges, G. E.; Housley, T. J.; Bhargava, A.; Wilhelm, S. M.; Shrikhande, A. "Discovery of a New Class of p38 Kinase Inhibitors" Bioorg. Med. Chem. Lett. 2000, 10 (18), 2047.	
		Proceedings of the American Association for Cancer Research - Volume 42 - March 2001 - #4957 A Novel Diphenylurea Raf-1 Kinase Inhibitor (RKI) Blocks the Raf/Mek/Erk Pathway in Tumor Cells. Scott McClelland Wilhelm et al., Bayer Corporation.	

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Application Number	10/042,226
Sheet	7	of	8	Filing Date	January 11, 2002
				First Named Inventor	Bernd RIEDL et al.
				Group Art Unit	1614
				Examiner Name	Dwayne C. Jones
				Attorney Docket Number	BAYER-0024-A

<b>NON PATENT LITERATURE DOCUMENTS</b>		
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
		Auclair, et al., "BAY 43-9006 (Sorafenib) is a potent inhibitor of FLT3 tyrosine kinase signaling and proliferation in AML cells," 96 <sup>th</sup> Annual Meeting, April 16-20, 2005, Anaheim/Orange County, CA
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		Clark et al., "Safety and pharmacokinetics of the dual action raf kinase and vascular endothelial growth factor receptor inhibitor, BAY 43-9006, in patients with advanced, refractory solid tumors," <i>Clin. Cancer Res.</i> , 2005;11(15), 1 August 2005, 5472-5480	
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		Eisen et al., "Phase I trial of BAY 43-9006 (sorafenib) combined with dacarbazine (DTIC) in metastatic melanoma patients," Meeting: 2005 ASCO Annual Meeting, Category: Melamona, Subcategory: Melamona, Abstract No. 7508	

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